IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, Plaintiff, vs. MYLAN INC., *et al*., Defendants.	Civil Action No. 17-2763 (FLW) (TJB) *Document Electronically Filed* Return Date: August 21, 2017 ORAL ARGUMENT REQUESTED

BRIEF OF DEFENDANTS MYLAN INC. AND MYLAN SPECIALTY L.P. IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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PRELIMINARY STATEMENT

Unable (or unwilling) to compete with Mylan on the merits of their respective epinephrine auto-injector products, Sanofi now seeks damages under the antitrust laws because Mylan allegedly offered discounts to pharmacy benefit managers and third-party payors. But the antitrust laws were designed to protect consumers by *promoting* lower prices, not to protect competitors by *punishing* lower prices. Sanofi claims that Mylan's discounts for the EpiPen® ("EpiPen") Auto-Injector and supposedly deceptive speech prevented Sanofi's Auvi-Q® ("Auvi-Q") product from gaining traction, but the antitrust laws provide no shelter to a competitor like Sanofi that is unable to allege that competition itself has been harmed. Each of Sanofi's claims should therefore be dismissed.

Failure to State Claim regarding Rebates. First, Sanofi's Complaint fails to state a claim based on Mylan's alleged rebates and price discounting to payors and pharmacy benefit managers ("PBMs"). Rebates and discounts are generally pro-competitive. Sanofi knows this well, and said so to this Court several years ago when it was itself faced with allegations of offering anticompetitive discounts to hospitals that allegedly kept competitors from accessing the hospitals' formularies:

> Using discounts to win business simply to increase sales is a pro-competitive outcome. It's perfectly lawful . . . ***even when done by companies in a so-called dominant position in the market***. There is nothing about having a successful product or a large market share that

> prohibits a company from going to customers and saying I'm going to give you an even bigger discount if you buy more from me.

Eisai, Inc. v. Sanofi-Aventis, U.S., LLC, No. 08-cv-04168, Tr. of Oral Argument, 6 (D.N.J. June 12, 2009), Dkt. 61 ("*Eisai*, Tr. of Oral Argument") (found at Calmann Decl. Ex. A) (emphasis added).

Sanofi ultimately won that case and the Third Circuit affirmed. Along the way, the Court reiterated that single-product rebates (which is what Sanofi alleges here) are only unlawful if the resulting prices are predatory, *i.e.*, below the defendant's cost of production. Here, Sanofi does not allege that Mylan's resulting prices were below cost because they indeed were not.

Sanofi now attempts to sidestep this black-letter law by alleging that Mylan's rebates were "conditioned" on exclusivity, but that theory fails too. Regardless of the labels a plaintiff applies, where the predominant mechanism of alleged exclusion is price—as it is here—there is no antitrust violation without below-cost pricing. *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 409 (3d Cir. 2016). And to the extent that Sanofi's rebate claims relate to alleged agreements with states or state agencies, those claims fail for the same reason, and additionally are barred by the *Noerr-Pennington* doctrine.

Failure to State Claim regarding Commercial Speech. Second, Sanofi's allegations that Mylan engaged in "deceptive conduct" to protect its supposed monopoly also fail to state a claim. Sanofi alleges nothing more than that Mylan

said things about the relative merits of EpiPen and Auvi-Q with which Sanofi disagrees. The law is clear, however, that commercial speech, even allegedly deceptive speech, almost never provides a basis for an antitrust claim. And this case is not one of the rare exceptions where it could.

Failure to State Claim regarding Alleged "Overall Scheme". Third, Sanofi cannot sustain its pleading burden by alleging that Mylan engaged in an "overall scheme" to monopolize. This claim largely repackages conduct alleged as part of the first two claims with conduct that is exempt from the antitrust laws under the *Noerr-Pennington* doctrine. Sanofi cannot state an antitrust claim by combining allegations that amount to lawful competition with other allegations of conduct that is exempt from the antitrust laws.

Failure to Allege Harm to Competition. Fourth, Sanofi's claims as a whole fail because Sanofi does not allege any facts indicating harm to competition, rather than just harm to Sanofi. Sanofi fails to allege that Mylan's alleged conduct freed Mylan from competition so that it could raise prices to consumers or reduce output or quality, which are the harms against which the antitrust laws protect. And Sanofi explicitly concedes that other competitors were not impacted by Mylan's alleged discounts.

Failure to Allege Causation. Finally, Sanofi fails to allege that whatever harm it claims to have suffered was caused by Mylan's alleged conduct. The

Complaint asserts in conclusory terms that Mylan's rebates and marketing practices made it hard for Sanofi to compete for certain sales, but the facts alleged reveal that Sanofi (1) *chose* not to compete on the terms that customers desired and then (2) stopped selling Auvi-Q altogether because it was forced to recall every single unit of the product from the market for safety reasons. The antitrust laws do not provide a remedy for such allegations.

BACKGROUND[1]

Defendant Mylan Inc. is a healthcare company focused on the development and marketing of branded and generic prescription drugs. Complaint (Dkt. 1) ("Compl.") ¶ 12 (found at Calmann Decl. Ex. B). A subsidiary of Mylan Inc., Defendant Mylan Specialty L.P., develops, manufactures, and markets prescription drug products for the treatment of life-threatening allergic reactions. *Id.* ¶ 13. Among other things, Defendants (together, "Mylan") market and distribute the EpiPen Auto-Injector, an epinephrine auto-injector ("EAI") device used in emergency situations to treat anaphylaxis, a life-threatening condition that can result from allergic reactions to foods, pets, insects, or exposure to allergens. *Id.* ¶¶ 1-2. The EpiPen Auto-Injector allows patients to quickly and safely self-administer a prescribed amount of epinephrine, a drug designed to counteract the effects of anaphylaxis, through a spring-loaded needle. Mylan has marketed the

[1] Mylan denies the allegations in Sanofi's Complaint but assumes the truth of those allegations solely for purposes of moving to dismiss under Rule 12(b)(6).

EpiPen Auto-Injector in the United States since 2007. *Id.* ¶ 38.

In January 2013, Plaintiff Sanofi launched Auvi-Q, an EAI device also used for the treatment of anaphylaxis. According to Sanofi, Auvi-Q was a "novel and advanced EAI drug device" that "quickly gained traction" when it launched. *Id.* ¶¶ 4-5. Less than three years later, in October 2015, "Sanofi undertook a voluntary recall of Auvi-Q following reports of manufacturing issues affecting some devices." *Id.* ¶ 110. Sanofi never re-launched the product, deciding instead to return its rights to kaléo, inc. *Id.* Though Mylan had nothing to do with the defects that compelled Sanofi's recall—and Sanofi does not allege that it did—Sanofi nonetheless claims that Mylan "contributed to its decision to forego its investment in Auvi-Q." *See id.* ¶ 110. The facts alleged in the Complaint, however, show that Mylan did nothing more than lawfully compete in the market.

As Sanofi explains, most EAI devices are sold to patients with health insurance. *Id.* ¶¶ 29, 32. Pharmaceutical companies like Mylan and Sanofi do not sell directly to these patients, but instead negotiate with, and sell product to, intermediaries, including third-party payors, PBMs and wholesalers. Third-party payors, including commercial health plans and government payors (such as Medicare and Medicaid), are incentivized to keep healthcare costs low. *See id.* ¶ 52. According to Sanofi, these payors, and the PBMs who "manage the pharmacy benefit of group health plan sponsors," obtain price discounts and rebates from

pharmaceutical companies.[2] *See id.* ¶¶ 30, 55. In turn, health plans and PBMs use tiered formularies to encourage patients to use those drugs that are less costly. *Id.* ¶ 34.

The documents Sanofi relies on in the Complaint provide important context for understanding Sanofi's allegations about competition between manufacturers for PBM formulary position. For example, a 2004 report by the U.S. Department of Justice and the Federal Trade Commission explains:

> The main tool that PBMs use to manage pharmacy benefits is the formulary, which is a list of PBM-approved drugs for treating various diseases and conditions. Through a formulary, the PBM controls the price that health plans and enrollees pay and may influence the use of various drugs and the mix of drugs dispensed. Panelists reported that although PBMs design formularies, plan sponsors often demand a customized formulary that addresses various needs of their enrollees (e.g., cost containment, access to certain medicines, high generic substitution, etc.)
>
> . . .
>
> Greater formulary compliance allows the PBMs to negotiate with the pharmaceutical manufacturer for better prices, because formulary compliance is an indication of the ability of the PBM to steer enrollees to various drugs. ***Thus, formulary compliance allows the PBM to negotiate what it can deliver for the manufacturers in terms of growth of their market share or avoidance of the manufacturers losing market share.***[3]

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[2] *See also* U.S. General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, 9 (Jan. 2003), http://www.gao.gov/assets/240/236828.pdf, cited at Compl. ¶ 36.

[3] U.S. Dep't of Justice & FTC, *Improving Health Care: A Dose of Competition*, Ch. 7, IV.B (July 2004),

Sanofi alleges that price rebates negotiated between Mylan and PBMs or third-party payors gave EpiPen devices preferred or exclusive position on certain formularies. Rebates are "common in the pharmaceutical industry," and are generally pro-competitive because they help "lower prices for end consumers, both when they pay for prescription drugs and when they pay health insurance premiums." Compl. ¶ 55. The 2004 DOJ/FTC report that Sanofi relies on explains that PBMs commonly negotiate rebates with manufacturers that can be based on any number of factors, including "achieving certain specified sales or market share targets" and/or "preferred placement of certain drug products on the PBM's formulary." *See DOJ-FTC Report, supra*, at 14. Although Sanofi focuses only on a narrow slice of competition in the industry—competition for formulary position—the DOJ/FTC report notes that PBMs use rebates to compete against each other to provide services to health plans. Specifically, PBMs compete to offer health plans the best package of financial terms from drug manufacturers and pharmacies as well as non-price terms, such as plan design. *Id*. And health plans consider these PBM packages holistically: "[f]or example, some want to maximize generic substitution, ***whereas others want to maximize rebates from manufacturers***." *Id*. at 15 (emphasis added).

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https://www.justice.gov/sites/default/files/atr/legacy/2206/04/27/204694.pdf, cited at Compl. ¶ 34 (emphasis added) ("DOJ-FTC Report").

Sanofi has recognized the procompetitive benefits of price discounts and rebates in prior litigation. Indeed, Sanofi advanced familiar arguments while defending an antitrust action in this District against allegations similar to those it now asserts against Mylan. In *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-cv-4168 (D.N.J. Filed Aug. 18, 2008), the plaintiff, Eisai Inc., marketed an anticoagulant, Fragmin®. Eisai sued Sanofi, alleging that Sanofi offered hospitals anticompetitive discounts on a competing drug, Lovenox® ("Lovenox"). *Eisai* Compl. ¶ 3 (Dkt. No. 1). Specifically, Eisai alleged that Sanofi entered into contracts with hospitals that required "a hospital customer purchase at least 90% of its relevant injectable anticoagulant purchases from Sanofi-Aventis to avoid losing a discount of up to 30% off the customer's total Lovenox purchases." *Id.* This condition, Eisai alleged, was a "pretext[] for . . . anticompetitive practices" and worked to exclude "actual and potential rivals from offering significant competition to Sanofi-Aventis by relegating these rivals to small market shares and denying them the ability to compete effectively across the entire market." *Id.* ¶¶ 5-6.

Sanofi moved to dismiss Eisai's complaint. (Dkt. No. 28-1). It argued that price discounts and rebates are "the very essence of competition" and that "courts are extremely reluctant to condemn any form of discount as anticompetitive." *Id.* at 10. It further argued that the "*sine qua non* of any antitrust complaint is an

allegation that the defendant has caused harm to competition" and that Sanofi's discount program was "nothing more than lawful, procompetitive price competition" that saved customers "millions of dollars." *Id.* at 9, 29. Eisai's claims were eventually dismissed, *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-cv-4168, 2014 WL 1343254, at *1 (D.N.J. Mar. 28, 2014), and the Third Circuit affirmed, 821 F.3d 394 (3d. Cir. 2016). Among other things, the appellate court concluded that "what Eisai call[ed] 'payoffs' were, in reality, discounts offered by Sanofi to its customers," 821 F.3d at 399, and that the discount program had neither harmed competition nor substantially foreclosed the relevant market, *id.* at 403-08.

In this matter, Sanofi has abandoned its former defense of discount programs. Like the plaintiff in *Eisai*, Sanofi now contends that the rebates allegedly offered by Mylan violated the antitrust laws because "Mylan used its monopoly market share and large rebates to coerce" insurance companies and PBMs into choosing Mylan over competition with Auvi-Q. Compl. ¶ 60. Importantly, Sanofi does not allege that Mylan's rebates resulted in prices that were predatory or below Mylan's cost of production. Nor does Sanofi allege that Auvi-Q was more affordable than EpiPen devices. On the contrary, Sanofi chose to launch Auvi-Q "at price parity with EpiPen," even though Mylan was purportedly charging monopoly prices. *Id.* ¶¶ 52, 91. Sanofi also alleges that other

competing sellers of EAIs were *not* excluded from PBM formularies by Mylan's conduct. *Id.* ¶ 59.

Sanofi claims that Mylan also engaged in other allegedly anticompetitive conduct. For example, Sanofi complains about a program in which Mylan gives away EpiPen Auto-Injectors to schools for free and a program in which Mylan gives patients coupons to cover their copays. *See id.* ¶¶ 80, 109. Not only do these programs provide substantial benefits for consumers, but Sanofi engaged in the very same conduct. After Sanofi launched Auvi-Q, it "matched" Mylan in many of the promotion programs it offered, including "a discount program for schools to have access to Auvi-Q" and "coupons to cover patient's [sic] co-pays." *Id.* ¶ 50. While Sanofi (falsely) alleges that Mylan required schools that received free EpiPen devices not to purchase other EAIs, even if that were true, Sanofi further alleges that such agreements were for no more than a year, *see id.* ¶ 80, and that "Mylan later eliminated the [nonexistent] requirement" altogether, *id.* ¶ 83. So even taking this canard on its face, it does not salvage an antitrust claim.

In addition, Sanofi claims that Mylan made misrepresentations about Auvi-Q. For example, Sanofi alleges that Mylan "created and spread misinformation about Auvi-Q and its bioequivalence to EpiPen." *Id.* ¶ 93. But no less an authority than the *FDA* concluded that the delivery systems of the two auto-injectors are not bioequivalent. *Id.* ¶ 48. Sanofi also alleges that Mylan misrepresented how Auvi-

Q was covered on formularies. *Id.* ¶ 97. Pointing to a flyer distributed by Mylan, Sanofi claims that Mylan told physicians that Auvi-Q was excluded from formularies "based on clinical recommendations, rather than on Mylan's huge, conditional rebate offers." *Id.* However, in the flyer itself, Mylan states that "[h]ealth plans and PBMs make formulary decisions based on internal clinical and financial recommendations." *Id.* Sanofi also alleges that Mylan misclassified the EpiPen Auto-Injector in the Medicare and Medicaid systems, which it used to "pay for the rebates that it offered to third-party payors." *Id.* ¶¶ 88-90. Sanofi does not explain how this allegation relates to its monopolization claims.

Based on these allegations, Sanofi asserts three counts against Mylan, all arising under Section 2 of the Sherman Act, 15 U.S.C. § 2. Sanofi alleges monopolization through exclusive dealing (Count I), monopolization through deceptive conduct (Count II), and an overall scheme to monopolize (Count III). Sanofi seeks damages based on the Auvi-Q sales it allegedly lost, the higher rebate costs it allegedly incurred, and the losses allegedly resulting from its return of the marketing rights for Auvi-Q back to the creators of the device. Compl. ¶¶ 137, 140, 143.

ARGUMENT

I. STANDARD OF REVIEW

To survive a motion to dismiss, a complaint must contain "more than an

unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." *Id.* (citation omitted). Rather, a complaint must contain factual "allegations plausibly suggesting (not merely consistent with)" unlawful conduct. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007). "In determining whether a complaint is sufficient, courts should disregard the complaint's legal conclusions and determine whether the remaining factual allegations suggest that the plaintiff has a plausible—as opposed to merely conceivable—claim for relief." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010); *accord Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011) ("This standard requires showing more than a sheer possibility that a defendant has acted unlawfully." (internal quotation marks omitted)).

This is particularly important in the antitrust context, where "proceeding to antitrust discovery can be expensive," and where "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Twombly*, 550 U.S. at 558 (internal quotation marks omitted). "While antitrust claims are subject to the notice-pleading standard of Federal Rule of Civil Procedure 8(a)(2), such claims must allege facts sufficient to raise a right to relief above the speculative level."

Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc., 602 F.3d 237, 246 (3d Cir. 2010) (alterations and internal quotation marks omitted). And while "[i]t is, of course, true that judging the sufficiency of a pleading is a context-dependent exercise," "[s]ome claims require more factual explication than others to state a plausible claim for relief." *W. Penn Allegheny*, 627 F.3d at 98 (citations omitted).

Sanofi sues under Section 2 of the Sherman Act, 15 U.S.C. § 2, which "makes it unlawful to monopolize, attempt to monopolize, or conspire to monopolize interstate or international commerce." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007). A Section 2 plaintiff must show "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Id.* at 307 (quotation omitted). "[T]he acquisition or possession of monopoly power must be accompanied by some anticompetitive conduct on the part of the possessor" and is "generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits." *Id.* at 308 (citation omitted). "Conduct that merely harms competitors, however, while not harming the competitive process itself, is not anticompetitive." *Id.*

II. SANOFI'S ALLEGATIONS REGARDING REBATES FAIL TO STATE A CLAIM.

Sanofi argues that Mylan responded to competition from Auvi-Q by

increasing the discounts it offered to PBMs and third-party payors and, as a result, won or kept business because the PBMs and payors got a better deal. That conduct is presumptively lawful as long as the discounts do not result in prices that are below the defendant's cost of production. Here, Sanofi does not allege that Mylan's prices are below Mylan's costs because it cannot, and Sanofi's rebate claims should therefore be dismissed. To the extent that Sanofi's claims relate to rebates or discounts offered to states or state agencies, Mylan's alleged conduct is also protected from antitrust liability by the *Noerr-Pennington* doctrine.

A. Sanofi fails to allege that Mylan's rebates resulted in below-cost pricing.

As Sanofi admitted to this Court several years ago, discounting "is the very essence of competition," Sanofi MTD in *Eisai* at 10. As a result, "courts are extremely reluctant to condemn any form of discount as anticompetitive." *Id*. at 10-11 (citing *Barry Wright Corp. v. ITT Grinnell Corp*., 724 F.2d 227, 234 (1st Cir. 1983) (Breyer, J.)). This is because "[l]ow prices benefit consumers regardless of how those prices are set." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993) (citation omitted). As the Supreme Court explained in *Brooke Group*, low prices do not threaten competition "so long as they are above predatory levels" because "the exclusionary effect of prices above a relevant measure of cost . . . reflects the lower cost structure of the alleged predator, and so represents competition on the merits . . . ." *Id*.; *see also Atl.*

Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 337 (1990) ("When a firm . . . lowers prices but maintains them above predatory levels, the business lost by rivals cannot be viewed as an 'anticompetitive' consequence . . ."). Moreover, "mistaken inferences" in cases "seeking to impose antitrust liability for prices that are too low," "are especially costly, because they chill the very conduct the antitrust laws are designed to protect." *Pac. Bell Tel. Co. v. Linkline Commcn's, Inc.*, 555 U.S. 438, 451 (2009) (internal quotations omitted); *see also* Sanofi MTD in *Eisai* at 10 ("To hold otherwise 'would, in effect, render illegal any decision by a firm to cut prices in order to increase market share.'") (quoting *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 116 (1986)).

Reflecting this concern, the only situation in which a plaintiff can state a claim for single-product rebates like the ones alleged by Sanofi is where the defendant engages in "predatory pricing." To state such a claim, a plaintiff must plead (1) that defendant set prices below cost and (2) a "dangerous probability" that defendant could recoup its losses once the plaintiff is excluded from the market. *Brooke Grp.*, 509 U.S. at 222-24; *see also Eisai, Inc.*, 821 F.3d at 408 (To state a claim, a plaintiff must show that "a firm reduce[d] its prices to below-cost levels to drive competitors out of the market and, once competition [was] eliminated, reduce[d] output and raise[d] its prices to supracompetitive levels."). These elements are critical in order to separate out truly exclusionary pricing

practices from what is "usually the case when a firm uses a single-product loyalty discount or rebate to compete with similar products . . .," which is that "an equally efficient competitor can match" those prices "and the firms can compete on the merits." *Eisai, Inc.*, 821 F.3d at 409. Where a plaintiff fails to allege either of these essential elements, such claims should be dismissed at the pleading stage. *Linkline Commc'ns*, 555 U.S. at 451-52 (predatory-pricing claim requires plaintiff to allege both below-cost prices "*and*" dangerous probability of recoupment; pleading-stage dismissal required when plaintiff alleged neither "of the *Brooke Group* requirements" (citing *Brooke Grp.*, 509 U.S. at 222-24)).[4]

Sanofi has not alleged—and cannot allege—that Mylan has priced EpiPen devices below cost, much less that it would be able to recoup any losses from below-cost pricing after Auvi-Q left the market. Thus, for the same reasons urged by Sanofi itself, its claims should be dismissed here for failure to state a claim. *See*

[4] The only other category of cases in which discounting has formed the basis for an antitrust claim is so-called "bundled discounts," where a firm has a must-have product and offers a discount on that product only if customers also agree to buy another product that is subject to competition. *See LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (involving allegations that 3M, which sold Scotch Tape, required customers to buy store brand tape from 3M in order to receive discounts on Scotch Tape, which was viewed by retailers as a "must have" product, and other products). This was the type of claim at issue in *Eisai*. Specifically, Eisai alleged that Sanofi, "having obtained a unique FDA indication" that other anti-coagulants lacked, "offered a discount that bundled incontestable [demand for the unique indication] and contestable demand" for competitive indications. *Eisai Inc.*, 821 F.3d at 409. Sanofi has alleged nothing of the sort here and so has not stated a bundling claim.

Sanofi MTD in *Eisai* at 11.

B. Sanofi cannot change the nature of its rebate allegations by calling Mylan's discounts "conditional rebates."

Sanofi claims that it is challenging Mylan's rebates because they are "conditioned on exclusivity." Compl. ¶ 65. But this re-casting of what is at bottom a price discount does not render the claims viable. As Sanofi itself previously told the Court, "***every*** plaintiff that brings a case challenging a discount program makes the same argument, that it's not a discount, it's a penalty…but it's still fundamentally a discount program." *Eisai*, Tr. of Oral Argument, supra, at 4. And the Third Circuit ultimately agreed with Sanofi, holding that when pricing is the means of exclusion at issue in a case, "the price-cost test applies." *Eisai, Inc.*, 821 F.3d at 409; *see also ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 274-75 (3d Cir. 2012) (Where "price is the clearly predominant mechanism of exclusion," the price-cost test is used as a "specific application of the rule of reason.'" (citation omitted)). The "price-cost test" means that the discount or rebate, even if tied to exclusivity, will only be unlawful if the defendant's price is below its costs, something Sanofi does not and cannot allege here. *Eisai*, 821 F.3d at 408.

It is plain from even a cursory reading of the Complaint that Sanofi alleges it was excluded as a result of a "pricing practice"—specifically "large rebates" allegedly offered by Mylan to third-party payors. Compl. ¶ 54; *see also id*. at ¶ 59 (explaining that it was rebates that "caused third-party payors to begin to restrict

the EAI drug device category . . . "); *id*. ¶ 63 ("Mylan excluded Auvi-Q from coverage in many states due to these rebates"); *id*. ¶ 71 (referring to "other pricing practices" that Mylan allegedly used to "block" Auvi-Q in addition to rebates). And while Sanofi makes much of the fact that these rebates were allegedly conditional, *id*. ¶¶ 59-60, the Complaint does not allege any facts showing that payors or PBMs entered into these deals for any reason other than to secure lower prices from Mylan. In fact, the Complaint is replete with references to the fact that it was the size of the rebates offered that made them appealing to payors and PBMs. For example, Sanofi alleges that Mylan used "large rebates to coerce third-parties to choose between accepting Mylan's huge rebates to exclusively cover the EpiPen, or foregoing those rebates…" *Id*. ¶ 60. Elsewhere Sanofi explains that the alleged exclusion occurred because "Mylan made third-party payors a never-before-made financial offer 'they could not refuse.'" *Id*. ¶ 65. Thus, even under Sanofi's telling, it was the financial appeal of these rebates—the reduction in prices—that convinced payors and PBMs to accept them.

The Third Circuit has held that allegations like these involving at most "the threat of a lost discount" are "a far cry from the anticompetitive conduct at issue" in prior cases where price was not the primary means of exclusion—namely *ZF Meritor*. *Eisai*, 821 F.3d at 407. In *ZF Meritor*, Eaton, the leading supplier of heavy-duty truck transmissions in North America, entered into "de facto exclusive"

supply agreements with *every* direct purchaser of such transmissions in the U.S. The agreements, which locked in the customers for at least five years, provided that Eaton would give the purchasers significant discounts for meeting market penetration targets and drove ZF Meritor out of the market. 696 F.3d at 263, 265. The court in *ZF Meritor* declined to apply the price-cost test, and instead applied exclusive dealing foreclosure analysis, because the plaintiff introduced evidence that compliance with the targets was "mandatory because failing to meet such targets would jeopardize the OEM's relationships" with Eaton and "losing Eaton as a supplier was not an option." *Id*. at 278; *see also Eisai*, 821 F.3d at 406. Thus, the court found that the long-term nature of the agreement and threat of loss of being terminated as a customer—not discounts or even the threat of a lost discount—was the driving force behind customers' choices. *ZF Meritor*, 696 F.3d at 277-78.

Sanofi alleges nothing of the sort here—only that the third-party payors risked losing a discount—and therefore the price-cost test applies.[5] And thus

[5] Other Circuits have also applied the price-cost test to rebates and discounts. *See NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 452-53 (6th Cir. 2007) (en banc) (affirming Rule 12(b)(6) dismissal of complaint alleging anticompetitive "up-front payments," i.e., rebates, in exchange for "the exclusive right to supply a set of stores" because "[t]hat [the defendant] offered greater discounts, though still non-predatory discounts, to win the retailers' business does not offend the antitrust laws, much less undermine the competitive environment those laws were designed to foster" (quotation omitted)); *accord Virgin Atl. Airways Ltd. v. British Airways*

without allegations of below-cost pricing, Sanofi's claims should be dismissed.

C. Sanofi's claims based on discounts or rebates to states or state agencies are barred.

Sanofi also asserts that Mylan's rebates excluded Auvi-Q from State Medicaid agencies' drug formularies. *See* Compl. ¶ 67. These claims fail for the same reason as those involving Mylan's rebates to PBMs and commercial payors—Sanofi has not alleged that these rebates resulted in below-cost prices. *See supra* Section I(B). Moreover, these allegations fail to state an antitrust claim under the *Noerr-Pennington* doctrine, which provides a "powerful shield" and "broad immunity" from the antitrust laws for conduct aimed at petitioning the government. *See Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 178 (3d Cir. 2015); *cert. denied*, 136 S. Ct. 2451 (2016). Mylan's alleged attempt to influence these State Medicaid agencies' drug policies and the agencies' final coverage decisions are precisely the sort of core First Amendment activities and governmental actions that *Noerr-Pennington* protects. *See E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961).

Bested competitors cannot state an antitrust claim based on a government decision to "enter[] into a contractual relationship with a private entity" when "the government engages in a policy decision and at the same time acts as a participant

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PLC, 257 F.3d 256, 269 (2d Cir. 2001) (affirming judgment in favor of defendant by applying price-cost test); *Barry Wright*, 724 F.2d at 232 (same).

in the marketplace." *Indep. Taxicab Drivers' Emps. v. Greater Hous. Transp. Co.*, 760 F.2d 607, 612-13 (5th Cir. 1985) (citation omitted); *see also Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606, 612–15 (D.N.J. 2000) (holding that the *Noerr–Pennington* doctrine immunized a drug manufacturer's exclusive commercial partnership with the National Cancer Institute to bring an anti-cancer drug to market). Yet that is precisely what Sanofi tries to do here. *Noerr-Pennington* precludes Sanofi's claims based on alleged discounts to state agencies.

III. SANOFI'S ALLEGATIONS REGARDING MYLAN'S SUPPOSEDLY DECEPTIVE SPEECH FAIL TO STATE A CLAIM.

Sanofi's allegations regarding supposedly deceptive speech by Mylan fare no better. "[I]t is the 'protection of competition or prevention of monopoly[ ] which is plainly the concern of the Sherman Act,' not the vindication of general 'notions of fair dealing,' which are the subject of many other laws at both the federal and state level." *Four Corners Nephrology Assocs., P.C. v. Mercy Med. Ctr. of Durango*, 582 F.3d 1216, 1225 (10th Cir. 2009) (Gorsuch, J.) (quoting PHILLIP E. AREEDA & HERBERT HOVENKAMP, Antitrust Law ¶ 770 (3d ed. 2008)). Thus, whatever injury Sanofi allegedly suffered from Mylan's supposedly deceptive speech, "it is not one that the antitrust laws were designed to remedy." *Id.* at 1227.

Long-standing Supreme Court precedent holds that "deception . . . can be of no consequence so far as the Sherman Act is concerned." *Noerr*, 365 U.S. at 145.

The Third Circuit and courts in this District have often reaffirmed this principle.[6] *See, e.g.*, *Santana Prods., Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 132 (3d Cir. 2005) (holding that plaintiff's allegations of fraud and deceptive conduct were "irrelevant" because 'deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned.'") (quoting *Noerr*, 365 U.S. at 145); *Eisai*, 2014 WL 1343254, at *37 (D.N.J. Mar. 28, 2014) (same).[7] As the Third Circuit explained in *Santana*:

> All of these arguments made by [the defendant] to its potential customers may have been wrong, misleading, or debatable. But they are all arguments on the merits, indicative of competition on the merits. To the extent they were successful, they were successful because the consumer was convinced by either [the defendant's]

[6] This is largely because advertising is presumed to have a "de minimis effect on competition." *Eisai*, 2014 WL 1343254, at *36 (citing to argument Sanofi made in briefing); *see also Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc.*, 323 F.3d 366, 370 (6th Cir. 2003) ("An antitrust claim premised primarily on advertising or speech must overcome a presumption that such advertising or speech had a *de minimis* effect on competition"); *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997) (same); *Nat'l Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs.*, 850 F.2d 904, 916 (2d Cir. 1988) ("[A] plaintiff asserting a monopolization claim based on misleading advertising must 'overcome a presumption that the effect on competition of such a practice was *de minimis*'" (citation omitted)). Sanofi has alleged nothing that even comes close to rebutting that presumption.

[7] So, too, have other Circuits. *See, e.g.*, *Retractable Techs., Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 896 (5th Cir. 2016), *cert. denied*, 137 S. Ct. 1349 (2017) ("[F]alse advertising alone hardly ever operates in practice to threaten competition" and thus hardly ever supplies the basis for an antitrust claim (citation omitted)).

> product or [the defendant's] salesmanship. [The defendant]—unsurprisingly—wanted to be picked over Stearns on a contract . . . Without a showing of some other factor, we can assume that a consumer will make his decision only on the merits. To the extent a competitor loses out in such a debate, the natural remedy would seem to be an increase in the losing party's sales efforts on future potential bids, not an antitrust suit.

Id. at 132-33 (quoting *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 524 (5th Cir. 1999)).

The same principles apply here. Sanofi contends that Mylan engaged in "misleading advertising and other promotional activities to harm Auvi-Q's reputation" by, for example, "creat[ing] and spread[ing] misinformation about Auvi-Q and its bioequivalence to EpiPen." Compl. ¶ 93; *see also id.* ¶¶ 94-96. For example, Sanofi alleges that Mylan used a "misleading title" for a study that was "not intended for legitimate scientific debate," but was instead aimed at influencing "the opinions of key thought leaders in the allergy field…" *Id.* ¶¶ 93-94. Sanofi also points to public statements and statements to physicians that it contends were "misleading." *Id.* ¶¶ 95-96. Sanofi further claims that, through this alleged conduct, Mylan "suggested the decision [by PBMs] to exclude Auvi-Q from formulary was based on clinical recommendation, rather than on Mylan's huge, conditional rebate offers." *Id.* ¶ 97. But, just as in *Santana*, even if Mylan made "wrong, misleading, or debatable" statements about Auvi-Q—a proposition Mylan denies and will disprove if this case proceeds—that still would not give rise

to an antitrust claim. *Santana*, 401 F.3d at 132-33; *see also Schachar v. Am. Acad. of Ophthalmology, Inc.*, 870 F.2d 397, 400 (7th Cir. 1989) (Easterbrook, J.) ("If such statements should be false or misleading or incomplete or just plain mistaken, the remedy is not antitrust litigation, but more speech—the marketplace of ideas.").

Sanofi is well aware of this limitation of the antitrust laws, and prevailed on precisely this argument in *Eisai*. The plaintiff in that case, like Sanofi here, alleged that Sanofi's deceptive marketing practices violated federal antitrust laws. 2014 WL 1343254, at *36-37. Sanofi countered that plaintiffs generally do not have a remedy "through the antitrust laws" for such conduct. *Id.* at *36. The Court agreed, noting that "[w]hile it is theoretically possible that 'false statements about a rival to potential investors and customers' can be a form of anticompetitive conduct, it would be a rare case in which such false statements in and-of themselves would be sufficient to support an antitrust violation." *Id.* (citing *Santana*, 401 F.3d at 132). Sanofi has alleged nothing here that would make this one of those "rare" cases. *See also id.* at *37 ("This is not such a rare case, and the Court has yet to find a case in this circuit that is that sort of rare case."); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 36371, at *8 n.7 (E.D. Pa. Jan. 4, 2017) ("Nothing about the nature of the SSRS process or the Complaint's allegations warrant deviating from

the general rule that deception is not actionable as an antitrust violation.").[8]

IV. NONE OF THE OTHER CONDUCT ALLEGED BY SANOFI STATES AN ANTITRUST CLAIM.

Sanofi devotes substantial space in the Complaint to allegations related to a variety of other conduct that it alleges, in conclusory fashion, to be "anticompetitive." Compl. ¶ 142. These additional allegations relate to Mylan's EpiPen4Schools program, price changes, Mylan's marketing claims, and discounts on copays. *Id*. ¶142.[9] Perhaps recognizing that these allegations have no plausible impact on competition, Sanofi haphazardly gathers them, along with the rebates to PBMs discussed above, under the permeable umbrella of a so-called "overall

[8] Sanofi's allegation that decisions to exclude Auvi-Q from formulary were based on Mylan's allegedly deceptive conduct, Compl. ¶ 97, is especially disingenuous in light of the fact that Eisai made precisely this argument in its suit against Sanofi, to which Sanofi responded that "[h]ospital administrators making formulary decisions are sophisticated and base their decisions on clinical data and other literature," rather than marketing tactics. *Eisai*, 2014 WL 1343254, at *36 (citing Sanofi briefing).

[9] While not referenced in relation to any of its claims, Sanofi also alleges that Mylan had "misclassif[ied] the EpiPen as a 'non-innovator' drug in the Medicare and State-based Medicaid space" and as a result, Mylan "had access to hundreds of millions of dollars…to pay for the rebates that it offered to third-party payors." Compl. ¶¶ 88, 90. Sanofi does not allege that this conduct is predatory or exclusionary, nor do the allegations relate to an element of any of Sanofi's claims and therefore Sanofi has not stated a claim with respect to these allegations. *Garshman v. Universal Res. Holding, Inc.*, 625 F. Supp. 737, 741 (D.N.J. 1986) ("[I]f he claims an antitrust violation, but the facts he narrates do not at least outline or adumbrate such a violation, he will get nowhere merely by dressing them up in the language of antitrust.") (quoting *Sutliff, Inc. v. Donovan Co.,* 727 F.2d 648, 654 (7th Cir. 1984); *Car Carriers, Inc. v. Ford Motor Co.,* 745 F.2d 1101, 1106 (7th Cir. 1984) (same)).

scheme." *Id*. None of these allegations, however, is sufficient to state a monopolization claim, alone or combined.

Sanofi wrongly alleges that Mylan's successful EpiPen4Schools program—*which provides hundreds of thousands of free EpiPen devices to schools*—was anticompetitive. *Id*. ¶ 142. In particular, Sanofi alleges that schools receiving free EpiPen devices had to agree not to purchase EpiPen devices from Mylan's competitors. *Id*. ¶ 80. However, even if this allegation were true (and it is not), Sanofi fails to allege that any competition foreclosed by such agreements "constitute[s] a substantial share of the relevant market" for a sufficient period of time, and therefore such allegations are insufficient to state a claim. *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 328 (1961); *see also Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 45-46 (1984) (rejecting antitrust claim regarding exclusive contract covering 30 percent of the market).

Sanofi also alleges that Mylan engaged in state and federal lobbying efforts to make it possible for schools to participate in the program, Compl. ¶¶ 77-79, which is immune from the antitrust laws under the *Noerr-Pennington* doctrine. *Noerr*, 365 U.S. at 135 ("[N]o violation of the [Sherman] Act can be predicated upon mere attempts to influence the passage or enforcement of laws"); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965); *In re Wellbutrin SR Antitrust Litig.*, Nos. 04-5525, 04-5898, 05-396, 2006 WL 616292, at *5 (E.D. Pa.

Mar. 9, 2006). Sanofi may not use *Noerr*-protected conduct "to support a claim of an overall scheme to monopolize if they cannot prove" that an exemption to the *Noerr* immunity applies. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D.N.J. 2006).

The rest of the conduct alleged in the Complaint amounts to no more than repackaged versions of the claims discussed above and thus fails for the same reasons as the rest of the Complaint.[10] For example, Sanofi alleges in conclusory fashion that Mylan "raised consumers' co-pay costs and Sanofi's costs for co-pay coupons." Compl. ¶ 142. Sanofi concedes that the only reason why it "had to pay significantly more to reimburse pharmacies for the $0 co-pay for Auvi-Q than Mylan did for the EpiPen" was because "the EpiPen, as the incumbent EAI drug device, was often listed at a higher coverage tier than Auvi-Q . . . ." *Id.* ¶ 33. Thus, according to Sanofi's own telling, Mylan was at a higher coverage tier due to its position as the incumbent and not as a result of any supposedly anticompetitive conduct. Any additional cost borne by Sanofi is the result of that fact and therefore

[10] Sanofi also includes in this Count allegations regarding Mylan's supposed "touting" of its superior formulary positioning "even when it didn't exclude Auvi-Q entirely . . ." Compl. ¶ 142. These allegations are no different than its inadequately pleaded claim related to Mylan's supposedly deceptive conduct, and should be dismissed for the same reasons. *See, supra,* Section II. In addition, by the very terms of these allegations, they relate to situations where Auvi-Q was not excluded, Compl. ¶ 142, and therefore cannot support a claim that this conduct was anticompetitive.

cannot support an antitrust claim. *Viacom Int'l Inc. v. Tele-Commc'ns, Inc.*, No. 93 CIV. 6658 (LAP), 1994 WL 561377, at *5 (S.D.N.Y. Oct. 12, 1994) ("[T]he theory of raising rival's costs does not apply to any increase in cost due to competition . . . ."); *see also, e.g., Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 784 F.2d 1325, 1339 (7th Cir. 1986) (explaining that raising a rival's costs may be anticompetitive only if the defendant is then able to "raise its own prices to consumers without drawing increased output from them"). At most, these allegations rehash Sanofi's complaints that it was forced to compete with Mylan on the basis of price—first for reimbursements by payors and PBMs and second for consumers who pay copays. Just as with Sanofi's allegations regarding Mylan's rebates to third-party payors and PBMs, Sanofi has alleged no facts that would establish that copay discounts were anticompetitive, and therefore these allegations do not state an antitrust claim. *Supra*, Section I.

It takes more to state a claim for an overall scheme to monopolize than to bundle together random facts that are at best extraneous to other claims in the Complaint. Sanofi does not merely "fail[] to prove an element essential to every claim," which alone makes aggregation of claims inappropriate, but indeed fails to allege facts that would establish any element of any claim. II PHILLIP E. AREEDA AND HERBERT HOVENKAMP, ANTITRUST LAW, § 310c (3d ed.). The "overall scheme" claim should therefore be dismissed. *City of Groton v. Conn. Light &*

Power Co., 662 F.2d 921, 928-29 (2d Cir. 1981) ("[W]e reject the notion that if there is a fraction of validity to each of the basic claims and the sum of the fractions is one or more, the plaintiffs have proved a violation of section 1 or section 2 of the Sherman Act.") (quoting *Ne. Tel. Co. v. Am. Tel. & Tel. Co.*, 651 F.2d 76, 95 n.28 (2d Cir. 1981)); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 78 (D.D.C. 2001) (After individually analyzing liability for separate acts, declining to find Microsoft liable by aggregating its entire "course of conduct").

V. SANOFI FAILS TO ALLEGE HARM TO COMPETITION.

Sanofi's antitrust claims also fail because Sanofi does not allege harm to competition. Sanofi fails to allege that Mylan's conduct led to increased prices or reduced output or quality because of reduced competition, and the exclusive dealing arrangements Sanofi alleges could not have harmed competition due to their short duration.

First, Sanofi fails to allege harm to competition because it does not allege that Mylan's conduct increased prices or restricted output or quality. "The antitrust laws . . . were enacted for 'the protection of competition not competitors.'" *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). A plaintiff "must prove more than injury causally linked to [defendant's conduct]. Plaintiffs must prove *antitrust injury*, which is to say injury of the type the antitrust laws were

intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp.*, 429 U.S. at 489 (emphasis added). In other words, "a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) (emphasis in original). "Without a showing of actual adverse effect on competition, [the plaintiff] cannot make out a case under the antitrust laws." *Jefferson Par. Hosp. Dist. No. 2*, 466 U.S. at 31.

In order to establish harm to competition, a plaintiff must show "reduced output, increased price, or reduced quality in goods or services." *Eisai,* 821 F.3d 403; *accord Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okla.,* 468 U.S. 85, 107 (1984) ("Restrictions on price and output are the paradigmatic examples of restraints of trade."). Harm to a *competitor*—unaccompanied by a reduction in output or quality or an increase in price—is never sufficient. *Brunswick Corp.*, 429 U.S. at 488.

Here, Sanofi does not allege that Mylan's rebates and discounts caused increased prices or reduced output or quality. On the contrary, Sanofi's allegations affirmatively demonstrate that there was competition and certainly no harm to competition or consumers. While Sanofi claims to have been excluded from certain formularies, it admits that other competitors were *not* excluded or allegedly harmed by Mylan's conduct. Compl. ¶ 59. And according to its own allegations,

Sanofi was free to compete for contracts with third-party payors but simply chose not to do so, as discussed below. *See infra*, Section VI. At bottom, Sanofi alleges that (1) Mylan began competing aggressively on price when it faced competition, and (2) third-party payors began placing EpiPen devices in a more advantageous formulary positioning than Sanofi when Mylan offered better pricing. Compl. ¶¶ 44, 52-54. These allegations do not describe harm to competition; they describe the very essence of competition.

In an attempt to square its claims with the antitrust laws, Sanofi claims that consumers were "deprived . . . of choice" in deciding between epinephrine auto-injectors. *Id*. ¶ 111. This is not harm to competition. Just because patients are not given "absolute choice" as to the products included on the formulary of their PBM or insurer "does not make it an anti-trust violation every time" a product is not granted optimal formulary positioning. *Bristow Endeavor Healthcare, LLC v. Blue Cross & Blue Shield Ass'n*, No. 16-CV-0057, 2016 WL 3199520, at *7 (N.D. Okla. June 8, 2016) (granting motion to dismiss allegations involving a health insurer's denial of in-network status to a healthcare provider), *aff'd*, 2017 WL 2350204 (10th Cir. May 31, 2017). Indeed, the very notion of a drug formulary or provider network is to keep overall costs down by limiting to some degree the options available to members to those that are the most clinically effective and cost-efficient. *See, e.g.*, *Ky. Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329,

332 (2003) (finding that insurers use selective contracting to "control the quality and cost of health-care delivery"); *Abraham v. Intermountain Health Care, Inc.*, 461 F.3d 1249, 1254 (10th Cir. 2006) ("[C]osts may decline and premiums may decrease when provider panels become smaller and more exclusive").[11]

The fact that competition for some customers allegedly involved competing to serve as an "exclusive" supplier is a "vital form of rivalry" encouraged and not *prohibited* by the antitrust laws. *ZF Meritor, LLC*, 696 F.3d at 270; *see also Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 83 (3d Cir. 2010) ("It is well established that competition among businesses to serve as an exclusive supplier should actually be encouraged."); *CAE Inc. v. Gulfstream Aerospace*

[11] While Sanofi alleges that Mylan raised *list* prices over the course of several years to defray the cost of rebates, Compl. ¶ 58, it does not allege that such increases were caused by Mylan's allegedly anticompetitive conduct and the Complaint does not identify list price increases as "harm to competition." Nor does Sanofi allege any facts regarding how these list prices impacted actual prices to PBMs or anyone else. Importantly, Sanofi also increased prices in parallel with, or higher than, Mylan. *See* Allan Coukell, Chuck Shih, & Emily Reese, *Beyond EpiPen: Prices of Lifesaving Epinephrine Products Soar*, THE PEW CHARITABLE TRUSTS, at Fig. 1 – Increasing Price of Epinephrine Auto-Injectors (Sept. 22, 2016), http://www.pewtrusts.org/en/research-and-analysis/analysis/2016/09/22/beyond-epipen-prices-of-lifesaving-epinephrine-products-soar (last visited July 26, 2017). Information regarding Sanofi's "relative" pricing of Auvi-Q—which is integral to the allegations in Sanofi's Complaint—can be considered on a motion to dismiss. *See, e.g.*, *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (citing *Pension Benefit Guar. Corp. v. White Consol. Indust., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). "[W]hen [a] plaintiff fails to introduce a pertinent document as part of his pleading, [a] defendant may introduce the exhibit as part of his motion attacking the pleading." Charles Alan Wright & Arthur R. Miller, *Fed. Prac. and Proc.* § 1327, at 762-63 (2d ed.1990).

Corp., 203 F. Supp. 3d 447, 455 (D. Del. 2016); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 663 (7th Cir. 2004); *Bob Maxfield, Inc. v. Am. Motors Corp.*, 637 F.2d 1033, 1036 (5th Cir. 1981) ("The mere existence of an exclusive dealing clause in a contract does not establish an antitrust violation."). The Seventh Circuit recently rejected a similar antitrust claim based on allegedly exclusive agreements, holding that "[c]ompetition-for-the-contract is a form of competition that antitrust laws protect rather than proscribe, and it is common." *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 411 (7th Cir. 2017) (Posner, J.) (internal quotations omitted). There, as here, the plaintiff hospital challenged allegedly exclusive agreements between the defendant hospital and third-party payors. *Id*. at 409. The court found that the agreements did not violate the antitrust laws, observing that such arrangements can result in benefits for the insurer and its members because "an insurance company may get better rates from a hospital in exchange for agreeing to an exclusive contract . . . ." *Id*. at 410. The same is true here with respect to benefits for both payors and patients.

Indeed, this form of competition for formulary position and exclusivity is common in the pharmaceutical industry. As Sanofi concedes, PBMs have an "incentive to provide preferential treatment to a lower-priced drug" when managing their formularies, Compl. ¶ 52, and "[e]ven rebates for exclusive coverage on a given third-party payor's drug formulary" are not unusual, *id*. ¶ 55.

Formulary management is a critical tool used by payors and PBMs to negotiate advantageous pricing for customers.[12] And there have been numerous widely-reported examples of situations where payors and PBMs have opted for exclusive arrangements to secure advantageous pricing for their customers.[13] Given the well-recognized benefits to competition for exclusive position, Sanofi cannot allege harm to competition simply by alleging that that it was excluded from certain formularies, which is all that it has done here.

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[12] *See* OECD, Directorate for Financial and Enterprise Affairs, *Competition Committee, Global Forum on Competition, Competition Issues in the Distribution of Pharmaceuticals, Contribution from the United States (Feb. 10, 2014)*, https://www.ftc.gov/system/files/attachments/us-submissions-oecd-other-international-competition-fora/pharmaceuticals_us_oecd.pdf ("PBMs typically use formularies both as a tool in negotiating discounts and rebates from manufacturers and as a means of steering covered persons to lower cost alternative therapies."); *see also* Thomas Reinke, *PBMs Just Say No to Some Drugs—But Not to Others, Managed Care* (April 2015), https://www.managedcaremag.com/archives/2015/4/pbms-just-say-no-some-drugs-not-others (quoting an executive at Express Scripts, one of the largest PBMs, as stating: "One of the ways we keep cost down for patients and payers is by managing the formulary. By being willing to exclude a handful of "me-too" products from our formulary, we have leverage to negotiate more effectively with manufacturers and ultimately achieve lower drug prices.").

[13] For example, in 2014, both CVS Health and Express Scripts chose to exclude GSK's Advair in favor of AstraZeneca's Symbicort and reversed their decision a year later "due to the improved pricing" they "were able to negotiate" for their customers. Carly Helfand, *Note to Big Pharma: Discounts Work. GSK price cuts score Advair a payer boost*, FiercePharma (Aug. 5, 2014), http://www.fiercepharma.com/sales-and-marketing/note-to-big-pharma-discounts-work-gsk-price-cuts-score-advair-a-payer-boost. Information regarding the manner in which PBMs use formulary management to achieve lower prices is integral to the allegations in Sanofi's Complaint and can be considered on a motion to dismiss. *See supra* n.11.

Second, Sanofi fails to allege harm to competition because Mylan's alleged agreements with PBMs were not long-term agreements with the potential to foreclose competition. As Judge Posner explained in *Methodist*, there can be no harm to competition when "most of the [challenged] contracts expire every year or two, giving other [firms], such as [the plaintiff], a shot at obtaining the next contract by outbidding [competitors]." *See Methodist Health Servs. Corp.*, 859 F.3d at 40. So too here. Sanofi alleges that the coverage decisions by third-party payors "typically last for one or two years." Compl. ¶ 67. Courts have long held that exclusive dealing arrangements of "short duration and easy terminability" can "negate substantially their potential to foreclose competition." *Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163-64 (9th Cir. 1997) (exclusivity arrangement allegedly foreclosing new entrant from market where all of defendant's distributors available within one year not anticompetitive); *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 394-95 (7th Cir. 1984) (en banc) (one-year contracts presumptively legal); *Paddock Publ'ns, Inc. v. Chi. Tribune Co.*, 103 F.3d 42, 47 (7th Cir. 1996) (same); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 237 (1st Cir. 1983) (Breyer, J.) (two-year contracts reasonable). When firms compete for a short-term contract and a competitor alleges that it cannot outbid another, courts have found that "the logical inference is that [the winning competitor] offered the [customer] a better deal . . . ." *Methodist Health Servs.*

Corp., 859 F.3d at 411; *see also Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1058 (8th Cir. 2000) (finding that allegedly de facto exclusive discount programs were really voluntary programs that the defendant's customers agreed to "because they individually got a deal from it").

VI. SANOFI FAILS TO ALLEGE THAT ITS INJURIES WERE CAUSED BY MYLAN'S ALLEGED CONDUCT.

Under the Sherman Act, a plaintiff must show that its injury was caused "by reason of" the defendant's anticompetitive conduct. 15 U.S.C. § 15(a). This requirement incorporates common-law principles of both but-for and proximate cause. *Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 531-33 & nn.24-28 (1983); *accord Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992). However, when an injury "[i]s attributable to . . . other factors independent of" the challenged conduct, a plaintiff has "not . . . met its burden." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 126-27 (1969). Under this framework, Sanofi cannot establish causation as a matter of law because (1) Sanofi alleges that it made an independent decision not to compete with Mylan, and (2) Sanofi alleges that it recalled Auvi-Q from the market for reasons unrelated to Mylan.

A. Sanofi admits that it made a unilateral decision not to compete with Mylan for exclusive or preferred formulary status.

Sanofi admits that it "had no intention of trying to make similar offers to

exclude the EpiPen from patients' coverage." Compl. ¶ 66. There is no allegation that it was unable to compete with Mylan for formulary positioning. Sanofi instead simply asserts that it "did not—and could not—try to take the EpiPen's place as the only covered product on a formulary." *Id.* ¶ 76. In explaining this decision, however, Sanofi has not alleged how Mylan's conduct foreclosed Sanofi's ability to compete. Rather, Sanofi relies on its own internal company judgments—namely that (1) "***Sanofi did not want*** to require patients…to wait for a doctor to revise a prescription" for EpiPen to one for Auvi-Q, (2) ***Sanofi "did not want*** to force any patients…to switch to Auvi-Q," (3) ***Sanofi had not*** achieved 100% market awareness for Auvi-Q, and (4) ***Sanofi was*** "confident that given equal access to Auvi-Q and EpiPen, patients would choose Auvi-Q…" *Id.* (emphasis added).

But unilaterally choosing to forego competing in the manner prescribed by the marketplace does not give rise to an antitrust claim simply because the market does not then respond positively. Whatever labels Sanofi now chooses to apply to its unwillingness or inability to compete effectively with Mylan, these allegations are at their core "not an antitrust issue," but rather "just them not wanting to compete on the merits." *Eisai*, Tr. of Oral Argument, *supra*, at 17; *accord City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (affirming dismissal of complaint when "any injury suffered by the [plaintiff] did not flow

from the defendants' conduct"); *cf. Read v. Med. X-Ray Ctr., P.C.*, 110 F.3d 543, 546 (8th Cir. 1997) (defendant did not cause plaintiff's injuries when plaintiff failed to "take reasonable steps to compete head-to-head").

Sanofi's Complaint falls short of plausibly alleging that it could not have matched Mylan's prices had it tried to compete for exclusive or preferred formulary positioning. For example, Sanofi claims that it would have had to "offer rebates far in excess" of those Mylan offered to persuade a third-party payor to forego "the Mylan rebate on the high percentage of the EAI drug device market that was held by the EpiPen." Compl. ¶ 61. However, this theory is predicated entirely on *Sanofi's own choice* to compete in a certain way. Had Sanofi chosen to compete for exclusive position on a PBM formulary, Mylan's allegedly "dominant" market share, *id*. ¶ 65, would not have mattered because Sanofi would have competed to supply all of the epinephrine auto-injectors for that particular PBM.[14]

Nor does Sanofi allege facts showing that it could not have competed on the basis of price in other ways. For example, Sanofi alleges that it would have had to

[14] There is nothing anticompetitive about high market shares, particularly involving successful first-in-class products, like the EpiPen Auto-Injector. *See United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945) ("The successful competitor, having been urged to compete, must not be turned upon when he wins."); *United States v. Syufy Enters.*, 903 F.2d 659, 665 n.6 (9th Cir. 1990) ("evidence of a high market share does not require a district court to conclude that there is an antitrust violation").

"offer rebates far in excess of the 30% rebates offered by Mylan," Compl. ¶ 61, but it does not explain why instead of trying to match Mylan's discounts and rebates, it could not have instead simply offered a lower list price rather than increasing list prices and offering rebates. This omission is particularly glaring given Sanofi's allegation that "because of Mylan's [list] price increases, Mylan's net prices on the EpiPen were soon higher after it began its exclusionary rebates than they were before the rebates began." *Id.* ¶ 58.

At bottom, Sanofi simply concludes that "Mylan's dominant EpiPen market share made it impossible for Sanofi to match Mylan's rebates." *Id.* ¶ 65. But if, as Sanofi alleges, "Auvi-Q represented a major innovation in the EAI drug device space that many patients and physicians preferred," *id.*, then third-party payors and PBMs would have nothing to fear in favoring Auvi-Q had Sanofi been willing to compete on price. Sanofi has previously described how companies faced with a large incumbent that is competing aggressively on price should react:

> [G]o to the customer and say, okay, I understand you have a good deal from [the other competitor]. . . I'll give you a better discount. Why don't you buy 90 percent of your requirements from me? Or why don't you buy 75 percent of your requirements from me and I'll give you a little bit more discount to compensate for that 25 percent?

Eisai, Tr. of Oral Argument, *supra*, at 8. Having chosen to abandon its own advice here, Sanofi's remedy is not an antitrust claim.

B. Sanofi was ultimately forced to exit the market due to a product recall, not Mylan's conduct.

Sanofi concedes that, as of October 2015, Sanofi had to recall ***all*** Auvi-Q devices from the market due to manufacturing issues. Compl. ¶ 110. There is no allegation that Mylan was involved in the decision to pull Auvi-Q from the market. Rather, Sanofi undertook this effort "voluntar[ily]." *Id.* As a result, Sanofi has failed to allege that Mylan caused any injuries that flow from the voluntary choice it made. *See W. Penn Power Co.*, 147 F.3d at 265.

CONCLUSION

For these reasons, Mylan respectfully requests that the Court dismiss Sanofi's Complaint with prejudice.

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